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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,354	04/12/2004	Bob M. Moore II	335,699-56	3071
34263	7590	01/05/2006	EXAMINER	
O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE 17TH FLOOR NEWPORT BEACH, CA 92660			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/822,354

Applicant(s)

MOORE, BOB M.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,7,10-15,17-20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,10-15,17-20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-6-05</u> . | 6) <input type="checkbox"/> Other: ____.   |

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The previous Office Action is vacated in favor of the following.

Claims 1-4, 7, 10-15, 17-20, 23-27 are generic to a plurality of disclosed patentably distinct species comprising a compound that has properties of cannabinoid receptor agonism and COX-2 inhibition. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In a telephone interview on December 16, 2005, Mr. Veravanich elected the species ajulemic acid. Accordingly, those methods of use directed to the administration of compounds having properties of cannabinoid receptor agonism and COX-2 inhibition, other than ajulemic acid, are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. The election was made without traverse.

An Amendment filed September 6, 2005 is acknowledged. Claims 5, 6, 8, 9, 16, 21 and 22 are canceled. Claims 1-4, 7, 10-15, 17-20, 23-27 remain under consideration.

A new title and Abstract are noted.

In the last Office Action claims 4 and 18 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite with respect to the limitation "wherein the COX-2 inhibitor is also a COX-1 inhibitor".

This rejection of record is withdrawn following an amendment to the claims which results in clear antecedent basis.

Following the cancellation of claims 5, 6 and 16 that were rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description, the rejection is moot.

Claims 17-27 were rejected in the last Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-24, 26 and 27 of U.S. Patent 6,916,852.

This rejection is withdrawn subsequent to the amendment to instant claim 17 in which the administration is clearly of a single compound.

In the last Office Action claims 1-4 and 7-15 were rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 7-9 and 13-16 of U.S. Patent 6,916,852.

This rejection is withdrawn subsequent to the amendment to instant claims 1 and 12 in which the administration is clearly of a single compound.

Claims 17 and 20-27 were rejected in the last Office Action under 35 U.S.C. 102(e) as being anticipated by Friary et al., US 2004/0010012. It was asserted Friary teaches the co-administration of the combination of a cannabinoid receptor agonist and a COX-2 inhibitor to treat shock.

This rejection is withdrawn subsequent to the amendment to instant claim 17 in which the administration is clearly of a single compound.

Claims 1-4, 7, 10-15, 17-20, 23-27 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, Applicant must convey with reasonable clarity, as of the filing date, that Applicant was in possession of the claimed invention. The issue of a lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996), (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that Applicant had possession of the claimed invention. An adequate

written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claims and determined that the invention would work for its intended purpose. An Applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Applicant was in possession of the claimed invention as a whole.

An Applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics that provide evidence that Applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

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A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. There are no working examples directed to causing constriction, increasing blood pressure and treating a subject suffering from or at risk of developing shock wherein ajulemic acid is administered. Applicant has not provided any working examples that would describe to one of ordinary skill in the art an embodiment that meets all the limitations thereof. Applicant has not described with sufficient clarity or provided support for the claimed methods of use. Sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent.

A review of the prior art, e.g., Drugs of the Future (2001), Drug Data Report, Drugs of the Future (2003), Burstein, S., Pharmacol. Ther. and Adam et al., Expert Opinion on Therapeutic Patents, fails to teach or suggest the administration of ajulemic acid for any cardiovascular endpoint.

The elected species appears to be free of the prior art.

No claim is allowed.

Applicant's Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

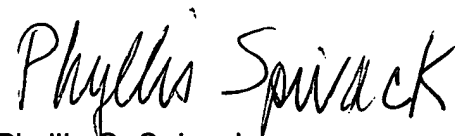


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 22, 2005



Phyllis G. Spivack

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**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**